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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,727	01/26/2001	Robert J. Ein	035887-0106	5192

7590 02/11/2003

Samuel B Smith Jr Stoll Keenon & Park LLP
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Suite 2100
Lexington, KY 40507-1801

EXAMINER

JEFFERY, JOHN A

ART UNIT	PAPER NUMBER
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3742

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/769,727

Applicant(s)

EIN, ROBERT J.

Examiner

John A. Jeffery

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 58 is/are allowed.
- 6) ☒ Claim(s) 1-23, 32-45 and 48-50 is/are rejected.
- 7) ☒ Claim(s) 24-31, 46, 47 and 51-57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>11</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

Restarting of Statutory Period

In response to applicant's communication dated 1/29/03 regarding the last Office action, the noted defects in the previous office action have been corrected.

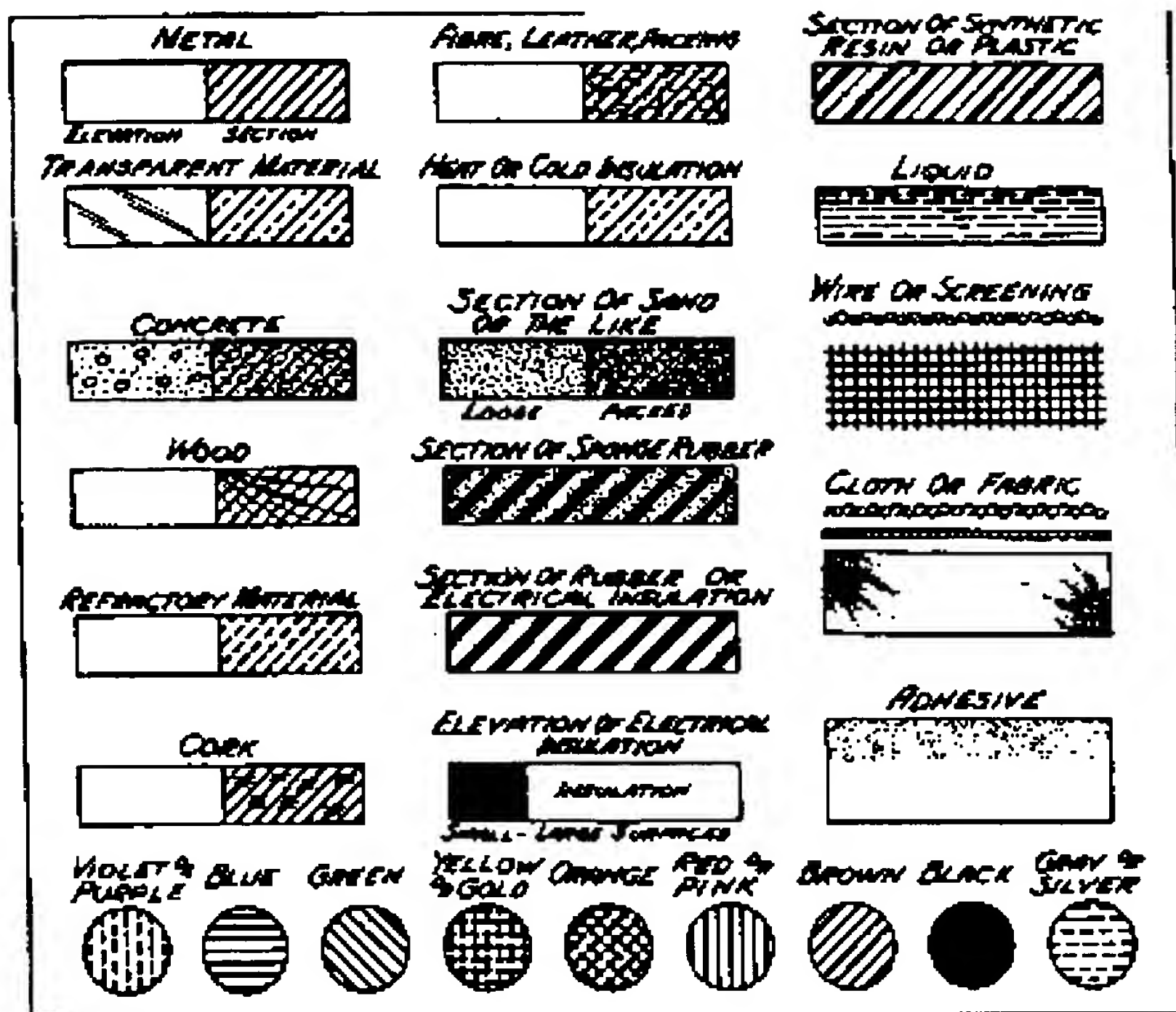
The period for response of 3 MONTHS set in said Office action is restarted to begin with the date of this letter.

A complete copy of the last Office action is enclosed.

Drawings

The drawings are objected to because of the following informalities:

Fig. 4A-4E: Proper cross-sectional hatching is required to properly denote *insulative and metallic* materials in accordance with MPEP 608.02 (see the drawing below for proper hatching examples).



All figures: The legends denoting the figure number must be enlarged for clarity.

The response to this action must include a separate letter addressed to the examiner and contain: (1) sketches showing in red the drawing changes required above and (2) a request that the examiner approve the changes as shown on the sketches.

IMPORTANT NOTE: The filing of new formal drawings to correct the noted defect may be deferred until the application is allowed by the examiner, but the print or pen-and-ink sketches with proposed corrections in red ink is required in response to this office action, and may not be deferred.

Claim Objections

Claims 3 and 4 are objected to because of the following informalities:

Claim 3: In line 5, "devise" must be changed to "device."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 10-14 and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 11: The test for indefiniteness under 35 U.S.C. § 112, second paragraph is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). In the last line, the term "said layer" is vague and indefinite since it is unclear, even when the claim is read in light of the specification, which layer is intended to be claimed. For purposes of examination, the examiner presumes "said layer" was intended to be "said lower layer."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7-9, and 23 are rejected under 35 USC 102(e)¹ as being anticipated by Johnston (US6023932). Note Peltier device 18 attached to the wrap adapted to be attached to the body. See Figs. 3 and 4. Note also control device in Fig. 4 and temperature sensors 40, 42 connected thereto.

Claims 1, 2, 5, 7-9, and 23 are rejected under 35 USC 102(b) as being anticipated by Patz et al (US5800490). Note Peltier device 85 attached to the wrap adapted to be attached to the body. See Figs. 1 and 3-11.

Claims 33 and 36-38 are rejected under 35 USC 102(b) as being anticipated by Nowak (US3132688). Note temperature sensor 16, controller 19 responsive to sensed temperature from sensor 16 to control the temperature via a "first switch" in the controller (see col. 3, lines 64-70), and a "second switch" comprising a toggle switch

¹ Despite arguments advanced by Applicant's attorney in the telephone interview on 1/29/03 that Johnston is potentially a §102(a) reference, and not a §102(e) reference, the examiner respectfully notes the examination guidelines regarding citation of §102(a) prior art are contrary to Applicant's assertion. See MPEP § 2132.01. The MPEP expressly states "when the reference is a U.S. patent publication within the year prior to the application filing date, a 35 U.S.C. 102(e) rejection should be made." Id. (emphasis added.)

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which reverses current flow through the Peltier device to heat or cool as desired (described in col. 3, lines 44-48, but not shown).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patz et al (US5800490) in view of Nowak (US3132688). The claims differ from the previously cited prior art in calling for the wrap to include a first port communicating with the TE device and temperature sensor and the control unit including a second port for releasable connection with the first port. Nowak (US3132688) discloses a control unit 19 with a cable which connects the control unit to both the Peltier device and the temperature sensor 16. See Fig. 1. According to col. 3, lines 56-59, a single cable could incorporate the leads 18 for the Peltier device and the leads 17 for the temperature sensor 16. While a releasable connection is not shown, it is well known to those skilled in the art to provide releasable electrical connections in the form of electrical connectors so that electrical connection is facilitated by merely connecting the electrical connector to the port. As is well known in the art, electrical connectors enable

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prompt and repeatable electrical connection enabling quick connection and disconnection. In view of Nowak (US3132688), it would have been obvious to one of ordinary skill in the art to use a single cable and electrical connectors in the previously described apparatus so that electrical connection is facilitated by merely connecting the electrical connector to the port.

Claims 1-5, 7-10, 23, 32, 33, and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman (US3648469) in view of Gray (US6024762), Nowak (US3132688), and further in view of Patz et al (US5800490). Chapman (US3648469) discloses a flexible therapeutic heating pillow with a Peltier device therein and a control 17. The claims differ from the previously cited prior art in calling for the pillow to be adapted to be secured to a body surface. Securing therapeutic pillows to body surfaces via straps is conventional and well known in the art as evidenced by Gray (US6024762) noting the last sentence of the Abstract and Fig. 7 wherein the pillow can be secured and worn by the patient. In view of Gray (US6024762), it would have been obvious to one of ordinary skill in the art to provide means for securing the pillow of Chapman (US3648469) to the body so that it can be worn by the patient thereby enabling therapeutic heating/cooling to be applied to the body while performing normal daily activities. The claims also differ from the previously cited prior art in calling for the control unit to be responsive to sensed temperature from a temperature sensor. Nowak (US3132688) discloses a heating/cooling pad with temperature sensor 16 and a controller 19 responsive to sensed temperature from sensor 16 to control the

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temperature via a "first switch" in the controller (see col. 3, lines 64-70), and a "second switch" comprising a toggle switch which reverses current flow through the Peltier device to heat or cool as desired (described in col. 3, lines 44-48, but not shown). In view of Nowak (US3132688), it would have been obvious to one of ordinary skill in the art to provide a temperature sensor and temperature-responsive control in the previously described apparatus so that heating and cooling was controlled responsive to the sensed temperature, thereby providing such temperature modification only when needed, thereby saving energy and prolonging the life of the apparatus parts. The claims also differ from the previously cited prior art in calling for the control unit being mountable to the wrap. While the control units are separate from the wrap in the previously described apparatus, Patz et al (US5800490) discloses a heating/cooling wrap which has a control unit mounted in a pocket within the wrap to enable convenient transport of the control unit during use. See Abstract, battery pack 99, and Figs. 4, 5. In view of Patz et al (US5800490), it would have been obvious to one of ordinary skill in the art to mount the control unit on the wrap of the previously described apparatus in order to enable convenient transport of the control unit during use. With regard to claim 3, Nowak (US3132688) discloses a control unit 19 with a cable which connects the control unit to both the Peltier device and the temperature sensor 16. See Fig. 1. According to col. 3, lines 56-59, a single cable could incorporate the leads 18 for the Peltier device and the leads 17 for the temperature sensor 16. While a releasable connection is not shown, it is well known to those skilled in the art to provide releasable electrical connections in the form of electrical connectors so that electrical connection is

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facilitated by merely connecting the electrical connector to the port. As is well known in the art, electrical connectors enable prompt and repeatable electrical connection enabling quick connection and disconnection. In view of Nowak (US3132688), it would have been obvious to one of ordinary skill in the art to use a single cable and electrical connectors in the previously described apparatus so that electrical connection is facilitated by merely connecting the electrical connector to the port.

Claims 6, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston (US6023932) or Patz et al (US5800490) in view of Nishida et al (US4633062). The claims differ from the previously cited prior art in calling for a pressure sensor mounted on the wrap for turning on the control unit when the sensor is activated. The use of pressure sensors as human body detection means in flexible, heated wraps is conventional and well known in the art as evidenced by Nishida et al (US4633062) noting "human body detecting means" 5 which comprises a pressure sensor (col. 4, lines 15-18) which provides a control signal to the control means for automatic temperature control. In view of Nishida et al (US4633062), it would have been obvious to one of ordinary skill in the art to use a pressure sensor in the previously described apparatus so that the presence or absence of the patient was detected via the pressure sensor thereby more accurately controlling the temperature of the patient.

Claims 6, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman (US3648469) in view of Gray (US6024762), Nowak (US3132688), Patz

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et al (US5800490), and further in view of Nishida et al (US4633062). The claims differ from the previously cited prior art in calling for a pressure sensor mounted on the wrap for turning on the control unit when the sensor is activated. The use of pressure sensors as human body detection means in flexible, heated wraps is conventional and well known in the art as evidenced by Nishida et al (US4633062) noting "human body detecting means" 5 which comprises a pressure sensor (col. 4, lines 15-18) which provides a control signal to the control means for automatic temperature control. In view of Nishida et al (US4633062), it would have been obvious to one of ordinary skill in the art to use a pressure sensor in the previously described apparatus so that the presence or absence of the patient was detected via the pressure sensor thereby more accurately controlling the temperature of the patient.

Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston (US6023932) or Patz et al (US5800490) in view of James (US5601618). The claims differ from the previously cited prior art in calling for at least one electrode to transmit a pulse to the body surface. Providing a flexible heating pad which also functions to deliver electrical pulses to the body is conventional and well known in the art as evidenced by James (US5601618) noting col. 3, lines 16-20 where a heating pad simultaneously provides electrical pulses to the patient for stimulation as well as heating. In view of James (US5601618), it would have been obvious to one of ordinary skill in the art to provide electrical pulses in conjunction with the heating/cooling effect of the previously described apparatus so that the patient was stimulated by the same

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apparatus that provided heating and cooling thereby providing three therapeutic functions (i.e., heating, cooling, and stimulation) in a single pad.

Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman (US3648469) in view of Gray (US6024762), Nowak (US3132688), Patz et al (US5800490), and further in view of James (US5601618). The claims differ from the previously cited prior art in calling for at least one electrode to transmit a pulse to the body surface. Providing a flexible heating pad which also functions to deliver electrical pulses to the body is conventional and well known in the art as evidenced by James (US5601618) noting col. 3, lines 16-20 where a heating pad simultaneously provides electrical pulses to the patient for stimulation as well as heating. In view of James (US5601618), it would have been obvious to one of ordinary skill in the art to provide electrical pulses in conjunction with the heating/cooling effect of the previously described apparatus so that the patient was stimulated by the same apparatus that provided heating and cooling thereby providing three therapeutic functions (i.e., heating, cooling, and stimulation) in a single pad.

Claims 34, 35, 39-45, 48, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman (US3648469) in view of Gray (US6024762), Nowak (US3132688), Patz et al (US5800490), and further in view of Chiurco et al (US4860748). The claims differ from the previously cited prior art in calling for a microprocessor having memory that stores at least one program for adjusting

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temperature over time. Providing a microprocessor with stored heating patterns to effect heating/cooling in a desired sequence is conventional and well known in the art as evidenced by Chiurco et al (US4860748) noting microcomputer 12 which provides a repeatable series of temperature patterns or sequences adjacent the area of pain on the patient's skin. See Abstract. In view of Chiurco et al (US4860748), it would have been obvious to one of ordinary skill in the art to provide a microprocessor in conjunction with the previously described apparatus so that multiple temperature control patterns could be utilized in lieu of a single heating paradigm, thereby tailoring the specific heating regime for a given patient or condition. With regard to claims 35, 39, and 40, digital thermostats are well known temperature sensors in the art for improved sensing accuracy, and batteries and fuel cells are well known mobile power sources in the art and their use does not constitute a patentably distinguishable characteristic of the invention. With regard to claim 50, current limiting devices in electronic power sources are conventional and well known protection devices in the art to prevent current inrush and overcurrent conditions and their use does not constitute a patentably distinguishable characteristic of the invention.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman (US3648469) in view of Gray (US6024762), Nowak (US3132688), Patz et al (US5800490), Chiurco et al (US4860748) and further in view of James (US6021348). The claims differ from the previously cited prior art in calling for the stimulation unit to comprise a waveform generator and modulator. Providing waveform generators and

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modulators to generate electrical stimulation signals in heating/stimulation pads is conventional and well known in the art as evidenced by James noting Fig. 1B and col. 4, lines 26-33 wherein a triangular waveform generator comprising a modulator includes an adjustable modulation rate. In view of James, it would have been obvious to one of ordinary skill in the art to include a waveform generator and modulator in conjunction with the previously described apparatus so that the modulation rate could be varied via the modulator thereby adjusting the stimulation effect as desired.

Allowable Subject Matter

Claims 24-31, 46, 47, 54-57, 51, 52, and 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 11-14 and 19-22 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112 and to include all of the limitations of the base claim and any intervening claims.

Claim 58 is allowable over the art of record.

Conclusion

Any inquiry concerning this or earlier communications from the examiner should be directed to John A. Jeffery at telephone number (703) 306-4601 or fax (703) 305-

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3463. The examiner can normally be reached on Monday-Thursday from 7:00 AM to 4:30 PM EST. The examiner can also be reached on alternate Fridays.

The fax phone numbers for the organization where this application or proceeding is assigned are:

Before Final (703) 872-9302

After Final (703) 872-9303

Customer Service (703) 872-9301

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0861.



**JOHN A. JEFFERY
PRIMARY EXAMINER**

2/7/03